

time along with the requisite fee extending the date for response to February 20, 2007.

Claims 1-9, 28-30 and 55 are now pending in the present application. Claims 1, 28 and 55 stand rejected under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement. The Office Action states that the term "a chemically induced unpleasant mouthfeel" was not described in the specification and since this term appears in the respective claims, the application does not meet the written description requirements of the first paragraph of 35 U.S.C. Section 112. It is further stated that the above-mentioned claims are indefinite under 35 U.S.C. Section 112, second paragraph, because the term "a chemically induced unpleasant mouthfeel" is a relative term which renders the claims indefinite. The rejections are hereby traversed and reconsideration is respectfully requested.

Applicants have previously indicated that one of ordinary skill in the art would note from the particular unpleasant mouthfeel effects identified on page 5, lines 1-2, that these would be chemically induced as opposed to physically induced. In addition, the meaning of this term is well recognized by those of ordinary skill in the art and indeed, is understood in the principle reference cited against the present claims (i.e. Katsuragi, EP 0732064).

Page 4 of the Office Action states that Katsuragi teaches adding at least one botanical, such as Ginko biloba in various compositions including hard-boiled candies. Thus, the prior art recognizes that botanicals are examples of components of foods that give rise to a problem of bitterness which are offensive tastes caused mainly by peptides and amino acids obtained from protein hydrolyzates and the bitterness of fruit juices (Katsuragi, page 2, lines 27-28). Thus, Katsuragi teaches that botanicals have a bitter taste caused mainly by various chemicals that are present in the botanical and how they are sensed within the oral cavity. Katsuragi uses the term "bitterness" as a short version of the term "chemically induced mouthfeel". One of ordinary skill in the art would recognize the relationship between the term "bitterness" and the term that is used in the present claims.

It should be noted that nowhere in the Katsuragi reference is the term "bitterness" defined. There is no qualitative or quantitative definition of the term "bitterness"; yet, Katsuragi is relied on to reject the present claims for what it fairly teaches. If the undefined term "bitterness" can be applied against Applicants' claims, then the term "chemically induced mouthfeel" (which means essentially the same thing) is sufficient to meet the standards of 35 U.S.C. Section 112. If not, Applicants' submit that Katsuragi is not a proper reference against the present claims because it fails to teach one of ordinary skill in the art what is meant by "bitterness".

Applicants, however, do not dispute that the term "bitterness" is a term recognized in the art in the same way that "chemically induced mouthfeel" is also

understood and recognized in the same art. For these reasons, the rejection of the claims under 35 U.S.C. Section 112 second paragraph (indefiniteness) should be withdrawn.

With regard to the written description (35 U.S.C. Section 112, first paragraph), it should be noted that the purpose of the written description requirement is to prevent an Applicant from later asserting that he invented that which he did not. "The Applicant for a patent is therefore required to recount his invention in such detail that his future claims can be determined to be encompassed within his original creation". Vas-Cath Inc. v. Mahurkar, 19 U.S.P.Q. 2d 1111, 1115 (Fed. Cir. 1991). Furthermore, satisfaction of the written description requirement is measured by the understanding of the person of ordinary skill in the art. Lockwood v. Am Airlines, Inc., 41 U.S.P.Q. 2d 1961, 1966 (Fed. Cir. 1997).

The issue involving the written description requirement is whether Applicants had possession of the invention which is now claimed such that the person of ordinary skill in the art would recognize the invention from those words which are used in the claim.

One of ordinary skill in the art would be very familiar with the "off-taste" of botanicals and minerals. The skilled artisan would also understand a number of terms that could be conveniently used to describe the sensation of the off-taste. One of those terms would be "bitterness" as used in Katsuragi. However, the term

“chemically induced mouthfeel” would be equally well-known, especially in view of the disclosure in the present application. For example, at page 1, lines 22-24 the unpleasant mouthfeel is described as soliciting a tingling sensation or “astringency”. In addition, page 5, lines 1-2 describe the unpleasant mouthfeel effects including tingling, burning, drying and astringency, all of which, like “bitterness” results from the interplay of various chemicals contained in the botanicals and mineral salts within the oral cavity.

Accordingly, there is ample support in the specification and a clear teaching to one of ordinary skill in the art of those types of ingredients that are encompassed by the term “chemically induced unpleasant mouthfeel”. In addition, one of ordinary skill in the art would know precisely what is meant by this term as recognized in Katsuragi which uses the term “bitterness” in essentially the same way.

It is therefore submitted that the term “chemically induced unpleasant mouthfeel” is described in the specification as filed and is a term which would be understood by those of ordinary skill in the art.

Claims 1, 2, 4-9, 28, 29, 31-36 and 55 are rejected as obvious over Katsuragi in view of Sharma (U.S. Patent No. 4,797,288) and Oravainen (WO 91/07100). The rejection is hereby traversed and reconsideration is respectfully requested.

Before discussing the rejection, it is important to note that the claimed invention is directed to a hard boiled candy composition and a hard gum composition, each of which contains either at least one botanical having a chemically induced unpleasant mouthfeel or at least one mineral or mineral salt exhibiting the same sensation. The chemically induced unpleasant mouthfeel is suppressed by the presence of from about 0.5% to about 5.0% by weight of one or more partially hydrogenated vegetable oils or saturated fats. Specific partially hydrogenated vegetable oils and saturated fats are listed in claim 4.

The Office Action states that Katsuragi teaches a bitterness-relieving agent which comprises an ester of a glyceride with a carboxylic acid or salt thereof. Thus, Katsuragi does not identify a bitterness-relieving agent as either a partially hydrogenated vegetable oil or a saturated fat. The bitterness-relieving agent is an entirely different compound; it is an ester. Page 9 of the Office Action states that the bitterness-relieving agent comprises an ester which Applicants agree is a correct statement. However, Applicants do not agree that the word "comprises" does not exclude components other than the ester as bitterness-relieving agents.

The word "comprising" is an open ended term that is used to determine the scope of a claim. The term "comprises" is not a substitute for an actual disclosure of a reference that is applied to the claims of the present application. For a reference to provide a teaching that is applicable to the patentability of the present application, there must be a teaching or suggestion of that additional component. The word

“comprising” is not a teaching or suggestion of any component which is not otherwise taught or suggested in the reference. The sole bitterness-relieving agents taught or suggested in Katsuragi are esters which are neither partially hydrogenated vegetable oils nor saturated fats as required in the present claims.

Further with respect to page 9 of the Office Action, the second paragraph provides an explanation about how the bitterness-relieving ester of Katsuragi is formed and concludes with the following statement. “Thus, the bitterness-reducing compound taught by Katsuragi is a fat based compound.” This statement is correct but irrelevant to the issue of patentability.

The present claims are directed to the use of partially of hydrogenated vegetable oils and saturated fats. Regardless of how the Katsuragi ester is made, it is an ester, a compound much different than Applicants' claimed unpleasant mouthfeel reducing agent. Applicants are not using esters but are using a well defined group of ingredients for relieving unpleasant mouthfeel. To arrive at the presently claimed invention from Katsuragi, one would have to dispense with the reaction that produces the required ester of the reference. In essence, one would have to disregard the Katsuragi teaching to arrive at the claimed invention. This is not permissible under 35 U.S.C. Section 103.

The third point made on page 9 of the Office Action is that the ester may be present with not more than 80% of other components. The cited portion of Katsuragi

(page 3, lines 39-43) is a further indication that the bitterness-relieving agent is the ester. The ester is the only component in the reference which is stated to provide a bitterness-relieving effect. The reference does say that unreactive components can remain but it is best to remove them to fortify the bitterness-relieving effect of the ester. In addition, the other components, which can include unreactive acids and glycerides as well as partially reacted by-products, may be present in amounts far exceeding the weight range of 0.5% to about 5.0% required for the partially hydrogenated vegetable oils and/or saturated fats employed in the present invention. In brief, page 3, lines 39-43 reinforces Katsuragi's invention of the use of an ester to achieve a bitterness-relieving effect. To the extent that other components may be present as by-products, one of ordinary skill in the art is not led to the present invention even if such by-products were present.

Page 9 of the Office Action (paragraph 4) again refers to the top of page 4 of Katsuragi as teaching the presence of an edible oil as a solvent for the bitterness-relieving agent. Applicants submit that this portion of the specification does not teach or suggest an edible oil as a bitterness-relieving agent required in the present claims.

As previously indicated, the present claims limit the agent which is used to suppress unpleasant mouthfeel to one or more partially hydrogenated vegetable oils and/or saturated fats in an amount of from about 0.5% to about 5.0% by weight. Katsuragi does not teach that edible oils used to dissolve the ester have any

bitterness-relieving effect. Once again, the only description in the reference of a bitterness-relieving effect is associated with the ester. In addition, Katsuragi describes edible oils which do not meet the criteria required in the present claims. The present claims require partially hydrogenated vegetable oils or saturated fats. Katsuragi includes as suitable solvents, animal fats and oils, fractionation products of animal fats and oils, transesterification products and the like, none of which are even similar to the agents used in the present invention to suppress unpleasant mouthfeel.

In addition, there is no mention and no teaching anywhere in Katsuragi of the amount of a desirable partially hydrogenated vegetable oil or saturated fat for use in suppressing unpleasant mouthfeel. The paragraph at the top of page 4 of Katsuragi discloses a solvent for the bitterness-relieving agent. Solvents are selected from a wide range of products many of which do not meet the criteria of Applicants' active agents. Furthermore, the skilled artisan is left to his own devices to figure out how much and what type of such agents could be used. There is no motivation for using the same as a bitterness reducing agent, instead there compounds are used solely as a solvent for a bitterness-relieving agent in the form of an ester, an entirely different agent than that claimed in the present invention.

Finally, page 9 of the Office Action indicates that the bitterness-relieving agent disclosed in Katsuragi is present in an amount of 0.1-10%. However, the bitterness-relieving agent is not a partially hydrogenated vegetable oil or a saturated fat. It is, in fact, an entirely different agent. It is an ester and the fact that an entirely different



agent is present in a similar amount to the agent employed in the present invention does not render the claimed invention obvious to one of ordinary skill in the art.

Further evidence of the teaching of Katsuragi can be seen from the working examples beginning on page 5. It will be noted from Table 2 on page 7 that when the ester is not used as a bitterness-relieving agent, the bitterness intensity of such reference examples which include mono-glyceride, di-glyceride and soybean lecithin are unacceptable. Thus, Katsuragi unequivocally teaches that it is the ester which provides the bitterness-relieving effect and not any other compound.

It necessarily follows that Katsuragi cannot be modified by Sharma or Oravainen. Sharma teaches away from the use of an ester to provide a bitterness-relieving effect but instead employs a hydrophobic matrix using an emulsifier, an edible material selected from fatty acids, natural waxes, synthetic waxes and mixtures thereof and at least one glyceride. Natural waxes and synthetic waxes of the type described at column 4, lines 27-36 are nowhere described in the present application. Emulsifiers which are critical to the hydrophobic matrix (column 2, lines 66) are listed at column 3, lines 38 to 63 and are likewise not employed in the present invention.

Furthermore, Sharma requires a hydrophobic matrix of all of these materials in order to coat pharmaceuticals. The coating of pharmaceuticals relates to a different technology as described in the present application at page 2, lines 5-15.

Pharmaceuticals are ingested very quickly. The purpose is to get the pharmaceutical as quickly as possible from the oral cavity to the gut. To the contrary, it is well known that hard candies and chewing gums are to be retained for extensive periods of time in the oral cavity. The taste masking issues associated with the claimed products are therefore quite different than those associated with rapidly ingested pharmaceuticals.

Oravainen discloses the addition of conventional processing agents and additives such as vegetable fat to a hard candy composition. There is no teaching or suggestion in this reference of the addition of botanicals or any other agent which induces an unpleasant mouthfeel. Given that Katsuragi requires an ester as a bitterness-relieving agent and that the same may be dissolved in edible oil, the teaching of Oravainen does not add anything further to the Katsuragi reference as it pertains to the present invention.

Applicants note the rejection of claims 3 and 30 based on the primary references as discussed above further in view of Ramont or Emmuanuel-King. The secondary references are cited to teach that Echinacea provides immune system benefits which are well known in the art. Applicants do not dispute that the benefits of Echinacea but submit the discovery of hard candy and gum compositions in which the unpleasant mouthfeel of botanicals and minerals are effectively suppressed using the requisite amount of partially hydrogenated vegetable oils and saturated fats is neither taught nor suggested by the references alone or in combination.

In view of the foregoing, Applicants submit that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

It is believed that no fee is due in connection with this matter. However, if any fee is due, it should be charged to Deposit Account No. 23-0510.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Allen R. Kipnes", written over the typed name and registration information.

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